IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES LISTED ON EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF NICOLE FLEISCHMANN, M.D.

Plaintiffs file this reply in support of their motion to exclude certain opinions and testimony proffered by Defendants Johnson & Johnson and Ethicon, Inc.'s ("Ethicon") expert Nicole Fleischmann, M.D. ("Dr. Fleischmann"), for all relevant TVT cases in this MDL. Ethicon has submitted Dr. Fleischmann to provide general causation opinions in certain Wave 1 cases[1] and case-specific opinions in certain cases.[2] In support of their Motion, Plaintiffs state as follows:

[1] *See* Exhibit A for a list of all cases in which Dr. Fleischmann has been identified as a general causation expert.

[2] A separate motion to exclude certain case-specific opinions proffered by Dr. Fleischmann has been filed in *Babcock v. Ethicon, et al.*, Case No. 2:12-cv-01052.

I. THIS COURT SHOULD EXCLUDE DR. FLEISCHMANN'S OPINIONS RELATED TO THE MATERIAL PROPERTIES OF TVT SYNTHETIC MESH

Ethicon argues that Dr. Fleischmann is a well-trained and experienced urogynecologist. That may be true, but Dr. Fleischmann does not have the requisite qualifications nor has she employed an appropriate methodology to render opinions regarding the material properties of TVT synthetic mesh, including pore size, degradation, and shrinkage.

A. Dr. Fleischman has insufficient knowledge, skill, experience, training and education to opine on topics related to the material properties of polypropylene mesh.

Dr. Fleischmann does not have any specialized education or training related to polypropylene or the scientific, chemical or structural make-up of the TVT mid-urethral sling and/or any of its components including polypropylene mesh.[3] Dr. Fleischmann has never analyzed, tested, or studied polypropylene mesh, and admits that she is not a materials expert.[4] Dr. Fleischmann seeks to testify that polypropylene does not undergo mechanical changes such as degradation and that degradation, if it occurs, does not have any clinical significance for patients.[5] Dr. Fleischmann opines that the TVT is composed of macroporous and monofilament "making it an excellent sling material."[6] In her report, Dr. Fleischmann states that the pore size of the TVT is entirely appropriate, but she has never studied pore size and the development of scar plate and bridging fibrosis at a cellular level.[7] Dr. Fleischmann has not participated in a study involving the histopathological analysis of mesh, including TVT mesh.[8] Because she is

[3] *Id.*
[4] *See* Ex. B at 31-36; Ex. C.
[5] Ex. B at 33.
[6] Ex. B at 32.
[7] *Id.* at 32; *See* Ex. D at 191:13-18; 192:22-195:11.
[8] Ex. D at 98:17-99:2; 194:2-195:22.

not a histopathologist,[9] Dr. Fleischmann defers to pathologists who analyze mesh material under the microscope.

Dr. Fleischmann's qualifications as a physician specializing in pelvic floor surgery are not sufficient to allow her to testify on design issues set forth above. Plaintiffs continue to direct the Court's attention to its decisions in *Tyree v. Boston Scientific Corp.* (excluding Dr. Bliavas),[10] and *Wise v. C.R. Bard, Inc.* (excluding Dr. Marshall Austin).[11]

Dr. Fleischmann has not participated in the design of a mid-urethral sling. Dr. Fleischmann has not studied pore size or the effect of pore size at the cellular level.[12] She has not participated in clinical trials involving mid-urethral slings.[13] The basis of Dr. Fleischmann's opinions regarding the design of the TVT is primarily her clinical experience. Dr. Fleischmann is not qualified and should not be allowed to testify regarding the design of the TVT.

B. Dr. Fleischmann does not use reliable methodology to form her opinions relating to the material properties of polypropylene.

1. Degradation

Dr. Fleischmann conceded that she has *never* done any of the following: tested polypropylene mesh[14]; looked at polypropylene under a microscope[15]; or sought out and/or reviewed any additional information from Ethicon regarding whether polypropylene mesh degrades.[16] Dr. Fleischmann's opinions are based primarily on the premise that since she herself has not identified a clinical outcome that in her mind correlates with degradation, then the mesh

[9] Ex. D at 221:7.
[10] 2014 WL 5320566 (S.D.W. Va. 2014).
[11] 2015 WL 570070 (S.D.W. Va. 2015).
[12] Ex. D at 194:22-196:22.
[13] Ex. D at 31:19-21.
[14] Ex. D at 31:19-21.
[15] Ex. D at 98:3-99:2.
[16] Ex. D at 204:14-205:6.

must not be degrading. Dr. Fleischmann testified that she reviewed literature and documents provided to her by Ethicon, but she did not ask Ethicon to provide her with all of the information that they have concerning degradation (only assumed that they would do so).[17] Dr. Fleischmann did not perform any specific research on her own.

The Court in *Winebarger v. Boston Scientific Corp.*[18] excluded Dr. Patrick Culligan from testifying to the design of pelvic mesh products, specifically regarding mesh properties including pore size, shrinkage, foreign body response and degradation:

> Although Dr. Culligan considered the scientific literature and his experience in forming these opinions, his deposition testimony reveals flaws in his method. In particular, his deposition testimony reveals that Dr. Culligan heavily relied upon his clinical experience in forming his opinions on pore size, shrinkage, foreign body response, and degradation, even though his experience with such topics is lacking.
>
> For example, Dr. Culligan testified that he has never measured under a microscope the pore size of any Uphold or BSC polypropylene mesh product. (Ex. C, Culligan Dep. (Jan. 12, 2015) [Docket 40–3], at 71:18–72:6). Although Dr. Culligan testified that his "best support for [the contention that mesh does not shrink] ... is [his] clinical experience[,]" he also testified that he has never measured patients' explants for shrinkage. (*Id.* at 349:9–14; 357:13–21). According to Dr. Culligan, he has not seen or felt shrinkage in his patients, and, thus, "mesh shrinkage ... is simply not a clinical problem that [he] recognize[s.]" (*Id.* at 358:5–18).
>
> Moreover, Dr. Culligan does not ask pathologists to examine his explants for chronic inflammation or foreign body response. (*Id.* at 311:22–312:4). He explains that he does not need to because "[t]hat's what [pathologists] do, that's their—that's their job." (*Id.* at 312:16–24). He declines to ask pathologists to test his explants for degradation because "[he'd] be asking them to look for something that [he] do[es]n't even believe happens." (*Id.* at 315:3–8). Dr. Culligan provides the following basis to supports his degradation opinions:
>
> > A: In a—in a clinically meaningful way, I do know how to assess for degradation, because I do it every time that I operate on a patient and do an explant. It's—the properties of mesh are apparent to me, and—when I'm removing a mesh, just like when I'm putting it in. And I don't—the—the clinical properties of the mesh

[17] *Id.* at 132:6-11.

[18] *Winebarger v. Boston Scientific Corp.*, 2015 WL 1509362, at 35 (S.D.W. Va. April 1, 2015).

are something I'm well aware of.

> (*Id.* at 315:12–22). Dr. Culligan's inherent awareness of "the clinical properties of mesh" is not a reliable basis to form an expert opinion. (*Id.*). Thus, his method is unreliable under *Daubert*. The plaintiffs' motion with respect to these opinions is **GRANTED.**

Though the Court found that Dr. Culligan considered the scientific literature, Dr. Culligan's deposition testimony revealed he relied heavily, if not primarily, on his clinical experience in forming his opinions. Similarly, Dr. Fleischmann also relies primarily on her clinical experience in reaching her opinion that mesh does not degrade. Dr. Fleischmann fails to employ reliable methodology in reaching her opinions on mesh material properties and they should be excluded just as Dr. Culligan's were in *Winebarger*.

2. Shrinkage and Contracture

Dr. Fleischmann states that medical literature does not provide evidence that the use of the TVT results in excessive contraction of tissues causing complications to patients. Dr. Fleischmann testified that she has not seen a correlation between contracture (along with fibrosis and scarring) and clinical symptoms in her practice.[19] A doctor's personal experience claiming to have not seen evidence of mesh shrinkage or contracture cannot serve as a reliable scientific basis for rendering an expert opinion. As noted above, the Court excluded the opinions of Dr. Culligan regarding shrinkage and contracture because although he considered the scientific literature he relied primarily on his clinical experience. The Court should exclude Dr. Fleischmann's opinions on shrinkage and contracture for the same reason.

Additionally, the Court should exclude Dr. Fleischmann's opinions on shrinkage and contracture because she failed to consider scientific literature that is contrary to her position.

[19] Ex. D at 192:22-193:21.

This Court recognized in *Tyree v. Boston Scientific Corp.*[20]: "An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." Though Dr. Fleischmann may have considered Dietz (2003) and Nilsson (2013), the overwhelming weight of the published scientific literature establishes mesh shrinkage as a generally accepted scientific phenomenon.

Dr. Fleischmann's reliance primarily on her clinical experience and her failure to consider or account for the abundant literature is contrary to her opinion, and therefore, renders her opinions unreliable.

II. THE COURT SHOULD EXCLUDE DR. FLEISCHMANN'S TESTIMONY ON THE TVT'S INSTRUCTIONS FOR USE ("IFU")

Dr. Fleischmann is not qualified to offer opinions regarding the adequacy of the TVT's IFU. In rendering her opinions regarding the TVT Retropubic IFU, Dr. Fleischmann did not consult published standards governing the information that should be included in a medical device warning.[21] Dr. Fleischmann did not review the testimony of Ethicon witnesses responsible for determining if the IFU's warnings were adequate and if the IFU complied with appropriate standards.[22] Dr. Fleischmann did not review Ethicon documents that address the standards or the criteria that it applied in determining what information should be included in the TVT IFU.[23] Dr. Fleischmann's opinions regarding what she would consider to be an adequate warning are based on her personal experience.[24]

Ethicon suggests that Dr. Fleischmann "reviewed and considered" the FDA's Device Labeling Guidance, various FDA public statements regarding surgical mesh, and statements

[20] 54 F. Supp. 3d 501, 520 (S.D. W. Va. 2014).
[21] Ex. D at 27:5-9.
[22] Ex. D at 27:12-19.
[23] Ex. D at 27:20-25.
[24] Ex. D at 28:1-7.

issued by numerous medical societies regarding the safety of pelvic mesh products, and "reviewed and analyzed" Ethicon's internal Standard Operating Procedure on Labeling, which addresses the contents of Instructions for Use, citing as the only support Dr. Fleischmann's reliance list.

Dr. Fleischmann's testimony refutes these assertions:

> Q. When you give your opinions about whether or not the warnings for the TVTTM Retropubic are adequate, are you applying any published standards for warnings?
>
> A. I don't understand the question.
>
> MS. KABBASH: Objection.
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> BY MR. SLATER:
>
> Q. Did you consult any published standards for what information is supposed to be provided in a medical device warning like for the TVTTM Retropubic?
>
> A. No.
>
> MS. KABBASH: Objection.
>
> BY MR. SLATER:
>
> Q. Did you review testimony by witnesses from Ethicon who are responsible for making sure the warnings are adequate, to see what standards they applied, in their industry, in determining what should be warned of? Did you look at those standards?
>
> A. I never looked at any testimony from Ethicon, no.
>
> Q. Did you look at any internal documents from Ethicon, where they set out the standards or the criteria that they applied in determining what information needed to be in a warning such as for the TVTTM Retropubic?
>
> A. I don't believe I have, no.
>
> Q. When you offer your opinions as to the adequacy of the warnings, are you essentially advising us what you believe would be

> adequate for you in your medical practice, with your basic – with your level of experience and what you're familiar with?
>
> A. Exactly, yes.[25]

In *Bellew v. Ethicon, Inc.*,[26] the Court excluded Dr. Denise Elser's opinions regarding an IFU. Dr. Elser is a board-certified urogynecologist and the Medical Director at the Women's Health Institute of Illinois. Dr. Elser testified that she based her opinions regarding the adequacy of the Prolift IFU on her clinical experience. The Court ruled that Dr. Elser's understanding of the possible risks associated with pelvic surgery is not enough to qualify her to offer opinions about the adequacy of the label. Also, in *Bellew*, the Court excluded the testimony of Dr. Christine Pramudji, also a board-certified urogynecologist, regarding the adequacy of the Prolift IFU on the same basis. In both instances, the Court quoted its decision in *Tyree* "that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included the risk [s]he observed in [her] own practice."[27]

For the same reasons, Dr. Fleischmann does not have the expertise to opine on product warnings, namely the TVT IFU. She is neither familiar with the standards applicable to medical device IFUs nor the process by which IFUs are developed and approved.[28] She does not rely on any standards nor information from Ethicon in rendering her opinions regarding the TVT IFU. Rather, she relies solely on her own personal opinion and experience.

Because Dr. Fleischmann lacks the necessary qualifications, and her opinions regarding the TVT IFU should be excluded.

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[25] Ex. Q at 26:23-28:7.
[26] No. 2:13-cv-22473, Order of Nov. 20, 2014, at p. 33 (S.D.W. Va.).
[27] *Tyree*, 54 F.Supp.3d at 584.
[28] *In re: C. R. Bard, Inc. (Cisson)*, 948 F. Supp. 2d 589, 611 (S.D.W.Va. 2013).

CONCLUSION

For the reasons above and in Plaintiffs' Memorandum in Support of the Motion to Exclude Certain Opinions and Testimony of Nicole Fleischmann, M.D., the Court should grant Plaintiffs' motion.

This 16th day of May, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ P. Leigh O'Dell_____
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